Commodity	Parts per million
Beet, sugar, molasses	2.0
Beet, sugar, roots	0.5
Beet, sugar, tops	15.0
Grass, forage	10.0
Grass, hay	0.2
Spinach	0.5
Sunflower, seed	0.5
Sunflower, meal	1.0
Tomato	0.1

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0328; FRL–7286–9]

Bacillus pumilus GB 34; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus pumilus* GB 34 when used as a seed treatment in or on soybeans and soybeans after harvest. Gustafson LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* GB 34.

DATES: This regulation is effective April 2, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0328, must be received on or before June 2, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Anne Ball, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8717; e-mail address: *ball.anne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Industry (NAICS 111), *e.g.*, crop production
- Industry (NAICS 112), *e.g.*, animal production
- Industry (NAICS 311), *e.g.*, food manufacturing
- Industry (NAICS 32532, *e.g.*, pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0328. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development.

To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of December 31, 2001 (66 FR 67522) (FRL–6813–8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 1F6344) by Gustafson LLC, 1400 Preston Road, Suite 400, Plano, TX 75093. This notice included a summary of the petition prepared by the petitioner Gustafson LLC. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *B. Pumilus* GB 34.

III. Risk Assessment

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information''

concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The *Bacillus pumilus* species was first described by Meyer and Gottheil in 1901. This naturally occurring species is one of the most numerous *Bacillus sp.* found on plant surfaces. The strain *Bacillus pumilus* GB 34 is a naturally occurring soil colonizer. The mode of action of the strain, an anti fungal agent, is to colonize the developing root system of the plant it is to protect, in this case the developing root system of the soybean plant. The organism *Bacillus pumilus* GB 34 then suppresses by competition, by the formation of a physical barrier, the continued formation of spores of the fungal diseases such as *Rhizoctonia and Fusarium*. Subsequently GB 34 colonizes the remaining fungal disease spores themselves, thereby destroying them. On the basis of Acute injection toxicity/Pathogenicity tests on rats, *Bacillus pumilus* GB 34 does not appear to be toxic, infective, and/or pathogenic in those mammals.

Toxicity studies submitted in support of this tolerance petition are summarized below. More detailed analyses of these studies may be found in the specific Agency reviews of the studies. Waivers requested and granted are, as well, noted.

Toxicity studies relating to the GB 34 Concentrate (End Use Product) and GB 34 Technical (Technical Grade Active Ingredient) are as follows:

1. *Acute oral toxicity*—i. *GB 34 Concentrate*. (Submitted to determine the adequacy of data to support an EUP, GB 34 Concentrate, and here, bridged to support a section 3 registration of the microbial product) (OPPTS 870.1100; OPP 152.30; Master record identification number (MRID) 452940–01). Five male and five female young adult Sprague-Dawley rats each received a single 5,000 milligrams/kilogram (mg/kg) gavage dose of GB 34 Concentrate, previously diluted to a 40% weight/weight (w/w) solution with distilled water at a dosing volume of 1 milliliter (mL)/100 grams (g). The rats were observed for morbidity, moribundity, and behavioral changes 1 and 3 hours after dosing and at least daily thereafter for 14 days. They were weighed on days 0, 7, and 14. At the end of the study, the rats were euthanized by CO_2 inhalation and necropsied. No morbidity, moribundity, or effects on body weight were found following treatment of rats with 5,000 mg/kg test material. Therefore, the Sprague Dawley rat oral lethal dose $(LD)_{50}$ of GB 34 Concentrate for male, female, and male and female combined is >5,000 mg/kg, placing the test material in Toxicity Category IV.

ii. *Acute oral toxicity—GB 34 Technical*. (OPPTS 870.1100; OPP 152.30; MRID 454335–01 corrected as MRID 457225–01). Five male and five female Sprague-Dawley rats each received a single 5,000 mg/kg gavage dose of the GB 34 Technical, previously diluted to a 40% w/w solution with distilled water, at a dosing volume of 1 mL/100 g. The rats were observed for morbidity, moribundity, and behavioral changes 1 and 3 hours after dosing and at least daily thereafter for 14 days. They were weighed on days 0, 7, and 14. At the end of the study, the rats were euthanized by CO_2 inhalation and necropsied. No morbidity, moribundity, or effects on body weight were found following treatment of rats with 5,000 mg/kg test material. Therefore, the Sprague Dawley rat oral LD_{50} of GB 34 Technical for male, female, and male and female combined is >5000 mg/kg, placing the test material in Toxicity Category IV.

2. *Acute dermal toxicity—GB 34 Concentrate and GB 34 Technical*. ((OPPTS 870.1200 and OPPTS 885. 3100 (Acute dermal toxicity/ Pathogenicity); OPP 152.31; waiver request, no MRID)). A waiver was requested and granted for a seed treatment use. The rationale for the waiver is that the rate of application of the product is 0.1 ounce (oz.) per 100 pounds (lbs.) of seed. The seed treatment is to take place in a commercial seed treatment facility in which there is no exposure to the general population. After germination of the treated seed, the habit of the bacterium is to inhabit the root system of the plant. There is expected to be minimal, if any, dermal exposure for the general population in a seed treatment use of the microbial pesticide.

3. *Acute inhalation toxicity—GB 34 Concentrate and GB 34 Technical*. ((OPPTS 870.1300 and OPPTS 885. 3150 (Acute pulmonary toxicity/ Pathogenicity); OPP 152.32; waiver request, no MRID)). A waiver was requested and granted for a seed treatment use. The use of GB 34 is to be limited to that of a seed treatment which is to take place in a commercial seed treatment facility in which there is no potential inhalation exposure to the general population. The rate of application of the pesticide is 0.1 oz. per 100 lbs. of seed. The habit of the bacterium is to gravitate to the root system of the developing plant. For a seed treatment use of GB 34 there will most likely be a negligible, if any inhalation exposure.

4. *Acute oral toxicity/Pathgenicity—GB 34 Technical and GB 34 Concentrate*. (OPPTS 885.3050). A waiver was requested and granted for a seed treatment use. The rationales such as are the minimal increase of human oral exposure expected due to the low rate of application (0.1 oz. per 100 lbs. of seed), the minimal exposure to the general population since the seed treatment will take place in a commercial seed treating facility with mechanical treating equipment, and the results of the toxicity tests submitted to date (see item 1.ii.) which do not indicate that this strain is toxic or infective. Moreover the results would suggest that the GB 34 strain does not express the 6,500 molecular weight toxin discussed in two papers. See item 7 below. In addition, the habit of the bacterium to gravitate to the root system of the developing plant makes it unlikely that any would be present in the above ground parts of the mature plant, thus minimizingthe potential for oral exposure for humans.

5. *Primary eye irritation*—i. *GB 34 Concentrate*. ((Submitted to determine the adequacy of data to support an EUP, GB 34 Concentrate, and here, bridged to support a section 3 registration of the microbial product) (OPPTS 870.2400; OPP 152.35; MRID 452940–02)). Three male and three female young adult New Zealand white rabbits were used in the experiment. Prior to test material instillation, both eyes were treated with 2% fluorescein and examined under ultraviolet (UV) light for ocular abnormalities. The test material, 0.1 mL (equivalent to 0.05–0.07 g), was instilled into the everted lower lid of the right eye and the upper and lower lids held closed for 1 second. The contralateral eye served as control. The eyes were examined and scored acording to the

Draize method 1, 24, 48 and 72 hours after test material instillation. The 24 hour examination also included a fluorescein staining examination for corneal effects. All rabbits survived the study. All rabbits developed slight conjunctival irritation that cleared within 48 hours of treatment. No corneal opacity or iritis were noted. GB 34 Concentrate was minimally irritating to the eye and is placed in Toxicity Category IV.

ii. *Primary eye irritation—GB 34 Technical.* (OPPTS 870.2400; OPP 152.35; MRID 454335–02, corrected as 457225–02). Three male and three female young adult New Zealand white rabbits were, prior to test, treated in both eyes with 2% fluorescein and then examined under UV light for ocular abnormalities. The test material, in the amount of 0.1 mL, was instilled into the everted lower lid of the right eye and the upper and lower lids were held closed for 1 second. The contralateral eye served as control. The eyes were examined and scored according to the Draize method 1, 24, 48 and 72 hours after test material instillation. The 24 hour examination also included a fluorescein staining examination for corneal effects. All rabbits developed moderate conjunctival irritation that cleared up within 72 hours of treatment. No corneal opacity or iritis or non-ocular effects were noted. The GB technical test substance was mildly irritating to the eye and is placed in Toxicity Category III.

6. *Primary dermal irritation*—i. *GB 34 Concentrate.* (Submitted to determine the adequacy of data to support an EUP for GB 34 Concentrate, and here, bridged to support a section 3 registration of the microbial product) (OPPTS 870.2500; OPP 152.34; MRID 452940–03). Three male and three female young adult New Zealand white rabbits were received for the study. The fur on the dorso-lumbar area of each rabbit was clipped. The rabbits were given a single 0.5 g dose of test material applied under a under a 1 inch x 1 inch 4-ply gauze pad on a 6 cm^2 clipped site. The gauze pad is then secured and Elizabethan collars were placed on the animals. Four hours later these were removed and the sites wiped with a moistened towel. The application sites were observed for dermal irritation 1, 24, 48, and 72 hours after patch removal. In addition the rabbits were observed at least daily for clinical signs of toxicity during the 72–hour study period. All rabbits survived the study. No dermal irritation was observed on any rabbit at any site. Based on the study GB 34 Concentrate is non-irritating to the New Zealand white rabbit and is placed in Toxicity Category IV.

ii. *Primary dermal irritation—GB 34 Technical.* (OPPTS 870.2500; OPP 152.34; MRID 454335–03 corrected as MRID 457225–03). Three male and three female New Zealand albino rabbits were prepared by clipping the dorsal area and the trunk. Only healthy animals without preexisting skin irritation had been selected for the test. The test substance in the amount of 0.5 g was placed on a 1 inch x 1 inch, 4-ply gauze pad which was applied and secured on each rabbit. After 4 hours exposure to the test substance, the pads were removed and the test sites gently wiped with water and towel to remove any residual test substance. Individual dose sites were scored according to the Draize scoring system at approximately 1, 24, 48 and 72 hours after patch removal. The animals were observed for signs of gross toxicity and behavioral changes at least once daily during the test period. All animals appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. No dermal irritation was noted at any test site during the study. Under the conditions of the study, the GB 34 Technical is classified as non-irritating to the skin and placed in Toxicity Category IV.

7. *Acute injection toxicity/Pathogenicity—GB 34 Technical.* (Submitted to determine the adequacy of data to support an EUP for GB 34, and here, bridged to support a section 3 registration of the microbial product) (OPPTS 885.3200; OPP 152.33; MRID 453416–01). A total of 39 male and 39 female rats were used in the tests. The results showed:

i. *Mortality.* No deaths were observed in any of the dosed or control groups prior to scheduled sacrifice.

ii. *Body and organ weights.* Overall, both male and female rats gained weight for the duration of the study, demonstrating the continued health of the animals.

iii. *Clinical Observation.* Overall, both male and female rats showed no abnormal clinical signs.

iv. *Gross necropsy.* No significant signs of abnormalities were seen except for a laceration on the left shoulder of a test substance treated male rat. An enlarged spleen was seen in one test substance treated male rat on day

The conclusion in the Data Evaluation report was that *Bacillus pumilus* GB 34 does not appear to be toxic, infective, and/or pathogenic in rats, when dosed at 1 x 10^7 cfu/animal. This test supports the requirements for both the TGAI (the technical) and the end use product (the concentrate).

A hypersensitivity study, or dermal sensitization study (OPP 152.36) is not required for registration of this product since the routes of use will not result ''in repeated human contact by inhalation or dermal routes'' as specified in footnote iii of the table in 40 CFR 158.740(c). Use of the product is limited to that of a seed treatment which takes place in a commercial facility using mechanical seed treatment equipment.

An Immune response study is not required for registration of this product because the Acute I.V., I. C., or I. P. Injection toxicity/Pathogenicity study, (OPPTS guideline 885.3200/OPP 153.33) submitted to determine the adequacy of data to support an EUP for GB 34, and here bridged support a section 3 registration of the microbial product, serves to address the endpoint of immune response. This injection study examines the normal functioning of the immune system when faced with the potentially most challenging exposure to this microbial pesticide active ingredient: Direct injection into the bloodstream. If the test animal is able to withstand and survive the introduction of such a large number of microbes, bypassing the normal protective barriers of the skin, the pulmonary macrophages and the gastrointestinal lymphoid tissues, then the immune system is functioning normally. The normal functioning of the immune system implies that it can recognize the introduced microbes as foreign and can clear them from the blood and other exposed organs. After the active ingredient, *Bacillus pumilus* GB 34 was intravenously injected into the test animals (rats), no deaths, adverse clinical signs or significant findings upon necropsy were seen 35 days after the injection. (See item 7).

The requirement for Tier II and Tier III data was not triggered because of the results of Tier I data which had been submitted or waived.

V. Aggregate Exposures

Section 408(b)(2)(D)(vi) of the FFDCA directs EPA to consider available information concerning aggregate exposures to consumers (and major identifiable subgroups of consumers) from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Bacillus pumilus GB 34 is a naturally occurring soil microorganism which

inhabits the root system of plants and acts as an antifungal agent. Review of the available toxicology data submitted in support of registration indicate that it is non-toxic and non-pathogenic to animals and humans. In its proposed use as a soybean seed treatment, it is not foreseen to contribute any or more than a negligible amount of dietary exposure.

1. *Food*. The product is used only as a seed treatment and the organism inhabits the roots of the plants, in this case the soybean plant roots. The use of products which contain *B. pumilus* GB 34 is not anticipated to result in more than negligible, if any, any dietary exposure from food for humans. To date there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to *B. pumilus* GB 34.

2. *Drinking water exposure*. There is expected to be only insignificant or minimal human exposure to the organism in drinking water from its use in the treatment of seeds, its only use proposed. The treatment of seeds is expected to take place in a commercial seed treatment facility. The farmer then plants the seeds in the soil. Since the organism is non-toxic and non-pathogenic to humans, even if small amounts would seep into the ground water, there is expected to be no adverse effect on humans.

B. Other Non-Occupational Exposure

The possibility for non-dietary exposure to residues of this *B. pumilus* pesticide for the general population, including infants and children, is unlikely because the only proposed use site is in an agricultural setting, as a treatment on soybean seeds. Since the seed treatment is to take place in a commercial seed treating facility where mechanical treating equipment is used, it is not expected that dermal or inhalation exposure to residues will occur in the general population, including infants and children. *Bacillus pumilus* GB 34 is a ubiqutous bacterium commonly found in soil, water, air and decomposing plant tissue and which acts as an antifungal agent. The bacteria typically occur at 106 to 107 colony forming units (CFU's) per gram of soil. It is not known to be pathogenic or toxic to any animal or plant species. The added soil density from the proposed seed treatment use rates represents a very small proportion of the naturally occurring bacilli in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus*.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to considered the cumulative effect of exposure to *B. pumilus* GB 34 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *B. pumilus* does not appear to be toxic or pathogenic to humans. Thus, there is no indication that the bacteria we consider here share any common mechanisms of toxicity (metabolic mechanisms) with other substances.

VII. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result from aggregate exposures to residues of *B. pumilus* GB 34, in its use as a seed treatment, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there is probably no potential for harm, from this bacterium in its use as a seed treatment via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Categories III and IV). Moreover no inhalation or dermal exposure is expected. FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the bacterium, *B. pumilus* GB34, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *B. pumilus* GB 34.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under FFDCA section 408(p) to develop a screening process to determine whether pesticide chemicals (and any other substance that may have an effect that is cummulative to an effect of a pesticide chemical) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effects effect as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen-and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been determined, *B. pumilus* GB 34 may be subjected to additional screening and/or testing to better characterize any effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for *B. pumilus* GB 34.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that analytical methods are not needed for enforcement purposes related to *B. pumilus* GB 34.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels nor any tolerances or exemptions issued for *B. pumilus* GB 34 outside the United States.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue

to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0328 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 2, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purpose of FFDCA section 408(m).'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0328, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Congressonial Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 12, 2003.

James Jones,

Acting Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.1224 is added to subpart D to read as follows:

§ 180.1224 Bacillus pumilus GB 34; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* GB 34 when used as a seed treatment in or on soybeans and soybeans after harvest.

[FR Doc. 03–7638 Filed 4–1–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0079; FRL–7297–8]

Modified Acrylic Polymers; Revision of Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises an existing exemption from the requirement of a tolerance for modified acrylic polymers when used as an inert ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemical formulations if such is used in accordance with good agricultural or manufacturing practices. Alco Chemical submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) requesting the revisions to the existing exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of modified acrylic polymers.

DATES: This regulation is effective April 2, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0079, must be received on or before June 2, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8373; e-mail address: alston.treva@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 25532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number